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SHERIDAN ROSS PC  
1560 BROADWAY  
SUITE 1200  
DENVER, CO 80202

EXAMINER

STEADMAN, DAVID J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

16

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,751

Applicant(s)

HUNTER ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-45, 49 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-45, 57 and 58 is/are rejected.
- 7) ☒ Claim(s) 49, 56 and 59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Application Status***

- [1]** Claims 43-45, 49, and 56-59 are pending in the application.
- [2]** Applicants' election without traverse of Group IV, claims 43-45, 49, and 56-60 in Paper No. 9, filed 01/10/03, is acknowledged.
- [3]** Applicants' cancellation of claims 46-48, 50-55, and 60 and amendment to claims 43-45, 49, and 56-59 in Paper No. 9 is acknowledged.

### ***Information Disclosure Statement***

- [4]** The information disclosure statement filed 07/25/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that references 3-6 are not present with the instant application or either of the parent applications (09/171,156 or 08/630,822). The remaining references have been considered. The examiner has made an earnest attempt to locate the missing references without success. The examiner requests copies of the missing references and upon receipt, will consider these references and return a copy of the IDS in a subsequent communication.

### ***Oath/Declaration***

- [5]** The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application serial number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: alteration to the zip code of inventor Gek-Kee Sim has not been initialed and dated as required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

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***Specification/Informalities***

**[6]** The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Flea Saliva Protein PfspI<sub>155</sub>". See MPEP § 606.01 regarding examiner's change in title.

***Claim Objections***

**[7]** Claims 44 and 45 are objected to because the term "*Ctenocephalidese*" appears to be spelled incorrectly. The term should be replaced with "*Ctenocephalides*". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**[8]** It is noted that claims 56 and 59 limit the polypeptide of claim 43 to being "PfspI<sub>155</sub>". The specification defines "PfspI<sub>155</sub>" as having the amino acid sequence of SEQ ID NO:62 (page 24, lines 10 and 11 and page 94, lines 16 and 17) and provides no indication that the term "PfspI<sub>155</sub>" is meant to be interpreted as any other protein besides SEQ ID NO:62. Thus, claims 56 and 59 are deemed to be definite in the meaning of the term "PfspI<sub>155</sub>" based on the definition provided in the specification.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**[9]** Claims 43-45, 57, and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 is drawn to (in relevant part) a genus of isolated proteins comprising a fragment of SEQ ID NO:62 having any function. Claims 44 and 45 limit the source of the genus of polypeptides of claim 43 to *Ctenocephalides* (claim 44) or *Ctenocephalides felis* (claim 45). Claim 57 limits the protein of claim 43 to a recombinantly produced protein. Claim 58 is drawn to a composition comprising the protein of claim 43. The specification teaches the structure of only nine representative species of such proteins, i.e., SEQ ID NOs:53, 62, 65, 70, 72, 75, 77, 78, and 87. The disclosure of these representative species fails to provide a sufficient number of representative species to adequately describe the entire genus of claimed polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than being a protein comprising a fragment of SEQ ID NO:62. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

**[10]** Claims 43-45, 57, and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO:62, does not reasonably provide enablement for any isolated protein comprising a fragment of SEQ ID NO:62 and optionally wherein the source of the polypeptide is limited to *Ctenocephalides* (claim 44) or *Ctenocephalides felis* (claim 45), or being a recombinantly produced protein (claim 57) or a composition comprising the protein (claim 58). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make and use the entire scope of claimed polypeptides. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art,

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(6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s). The Factors most relevant to the rejection are addressed below.

- Breadth of the claims: the claims are so broad as to encompass *any* isolated protein comprising a fragment of SEQ ID NO:62 and optionally wherein the source of the polypeptide is limited to *Ctenocephalides*, or *Ctenocephalides felis*, or being a recombinantly produced protein, or a composition comprising the protein. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims. In this case, the disclosure is limited to SEQ ID NO:2.

- The amount of guidance and working examples: the specification fails to enable methods of making and using the entire scope of claimed polypeptides. While the specification provides working examples describing methods of isolating at least nine different *Ctenocephalides felis* polypeptides, these working examples and the disclosure provided in the specification fail to provide guidance enabling a skilled artisan to isolate *any* protein, *any Ctenocephalides* protein, or *any Ctenocephalides felis* protein. Furthermore, the specification discloses the utility of the proteins isolated from *Ctenocephalides felis* as being used for identifying those allergens associated with flea allergy dermatitis (FAD). One of skill in the art would recognize that the broad scope of claimed polypeptides would not be so useful as the majority of such proteins would not be involved in FAD. The specification fails to provide guidance for using those proteins that are not associated with FAD.

- The unpredictability of the art: one of skill in the art recognizes that the methods used for isolating the nucleic acid sequences encoding the disclosed proteins, i.e., hybridization and PCR, are dependent on the structures of the encoding nucleic acid sequences. Thus, these methods would not be applicable for isolating encoding nucleic acid sequences with structures that are highly variant from those disclosed in the specification. Therefore, the likelihood of isolating all polypeptides within the scope of the claims using the methods as disclosed in the specification is highly unpredictable. Furthermore, it is highly unpredictable as to whether these proteins would be involved in FAD.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

**[11]** It is noted that claims 56 and 59 limit the polypeptide of claim 43 to being "PfspI<sub>155</sub>". The specification defines "PfspI<sub>155</sub>" as having the amino acid sequence of SEQ ID NO:62 (page 24, lines 10 and 11 and page 94, lines 16 and 17) and provides no indication that the term "PfspI<sub>155</sub>" is meant to be interpreted as any other protein besides SEQ ID NO:62. Thus, claims 56 and 59 meet the written description and enablement requirements of 35 USC 112, first paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**[12]** Claims 43-45 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath et al. (US Patent 5,356,622; IDS reference 1). Claim 43 is drawn to (in relevant part) a protein comprising a fragment of SEQ ID NO:62. Claims 44 and 45 limit the protein of claim 43 to a *Ctenocephalides* protein (claim 44) or a *Ctenocephalides felis* protein (claim 45). Claim 58 is drawn to a composition comprising the protein of claim 43. Heath et al. teach isolation of *Ctenocephalides felis* flea midgut antigen proteins (see column 8) for use in generating antibodies. This anticipates claims 43-45 and 58 as written.

**[13]** Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (*Proc Natl Acad Sci USA* 90:11980-11984). Claim 57 limits the protein of claim 43 to a recombinantly produced protein.

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Yang et al. teach a recombinantly produced aspartate transcarbamoylase (see page 11981, right column). This anticipates claim 57 as written.

**Conclusion**

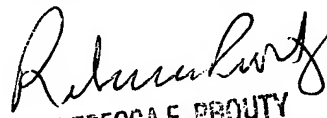
**[14]** Claims 49, 56, and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**[15]** Claims 43-45, 57, and 58 are rejected.

**[16]** The examiner can find no teaching or suggestion in the prior art directed to the polypeptide of SEQ ID NO:62.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for official papers filed to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1600  
1600